

IFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Paul C. Harris and Brian Richards

Application No.: 10/714,318 Group Art Unit: 1641

Filed: November 14, 2003 Examiner:

Confirmation No.: 9689

Title: COMPENSATION FOR VARIABILITY IN SPECIFIC  
BINDING IN QUANTITATIVE ASSAYS.

|   |              |
|---|--------------|
| CERTIFICATE OF MAILING OR TRANSMISSION  |              |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: |              |
| 6/8/04  | Katie Norris |
| Date  | Signature    |
| Katie Norris  |              |
| Typed or printed name of person signing certificate   |              |

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

- ☐ Copies of the cited references are enclosed.
  - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/817,781, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [       ] under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [     ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[     ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

*David E. Brook for R.N. 22592*

By *Elizabeth W. Mata*

Elizabeth W. Mata

Registration No.: 38,236

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: *6/9/04*

PTO-1449 REPRODUCED

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

June 8, 2004

(Use several sheets if necessary)

 ATTORNEY DOCKET NO.  
2065.2001-006

 APPLICATION NO.  
10/714,318

 FIRST NAMED INVENTOR  
Paul C. Harris

 FILING DATE  
November 14, 2003

EXAMINER

CONFIRMATION NO.

 GROUP  
1641

**U.S. PATENT DOCUMENTS**

| EX-<br>INER<br>INI-<br>TIAL | REF.<br>NO. | DOCUMENT NUMBER<br>Number-Kind Code (if known) | ISSUE DATE /<br>PUBLICATION DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT |
|-----------------------------|-------------|--|--|--|
|                             | AA          | 5,356,782                                      | 10-18-1994                                     | Moorman, <i>et al.</i>                             |
|                             | AB          | 5,384,264                                      | 01-24-1995                                     | Chen, <i>et al.</i>                                |
|                             | AC          | 5,458,852                                      | 10-17-1995                                     | Buechler   |
|                             | AD          | 5,506,114                                      | 04-09-1996                                     | Sangha   |
|                             | AE          | 5,569,589                                      | 10-29-1996                                     | Hiraoka, <i>et al.</i>                             |
|                             | AF          | 5,569,608                                      | 10-29-1996                                     | Sommer   |
|                             | AG          | 5,610,077                                      | 03-11-1997                                     | Davis, <i>et al.</i>                               |
|                             | AH          | 5,622,871                                      | 04-22-1997                                     | May, <i>et al.</i>                                 |
|                             | AI          | 5,648,274                                      | 07-15-1997                                     | Chandler, <i>et al.</i>                            |
|                             | AJ          | 5,656,503                                      | 08-12-1997                                     | May, <i>et al.</i>                                 |
|                             | AK          | 5,753,517                                      | 05-19-1998                                     | Brooks, <i>et al.</i>                              |
|                             | AA2         | 5,851,048                                      | 12-22-1998                                     | Fujita, <i>et al.</i>                              |
|                             | AB2         | 5,885,527                                      | 03-23-1999                                     | Buechler   |
|                             | AC2         | 6,133,048                                      | 10-17-2000                                     | Penfold, <i>et al.</i>                             |
|                             | AD2         | 5,141,850                                      | 08-25-1992                                     | Cole, <i>et al.</i>                                |
|                             | AE2         | 6,103,536                                      | 08-15-2000                                     | Geisberg   |
|                             | AF2         | 6,136,610                                      | 10-24-2000                                     | Polito, <i>et al.</i>                              |
|                             | AG2         | 6,436,721                                      | 08-20-2002                                     | Kuo, <i>et al.</i>                                 |
|                             | AH2         |  |  |  |
|                             | AI2         |  |  |  |
|                             | AJ2         |  |  |  |
|                             | AK2         |  |  |  |
|                             | AA3         |  |  |  |
|                             | AB3         |  |  |  |
|                             | AC3         |  |  |  |

EXAMINER

DATE CONSIDERED

|  |   |                                      |   |
|--|---|--------------------------------------|---|
| <b>PTO-1449 REPRODUCED</b><br><br><b>INFORMATION DISCLOSURE CITATION<br/>IN AN APPLICATION</b><br><br><b>June 8, 2004</b><br><br>(Use several sheets if necessary) | <b>ATTORNEY DOCKET NO.</b><br>2065.2001-006   | <b>APPLICATION NO.</b><br>10/714,318 |   |
|  | <b>FIRST NAMED INVENTOR</b><br>Paul C. Harris |                                      | <b>FILING DATE</b><br>November 14, 2003 |
|  | <b>EXAMINER</b>                               | <b>CONFIRMATION NO.</b>              | <b>GROUP</b><br>1641                    |

### FOREIGN PATENT DOCUMENTS

|  |     | DOCUMENT NUMBER<br>Country Code-Number-Kind Code<br>(if known) | DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT | TRANSLATION<br>YES NO |  |
|--|-----|--|--------------------|--|-----------------------|--|
|  | AL  | WO 88/08534  | 11-03-1988         | Unilver  |                       |  |
|  | AM  | WO 93/03175  | 02-18-1993         | Serex  |                       |  |
|  | AN  | WO 97/09620  | 03-13-1997         | Agen Biomedical Limited                            |                       |  |
|  | AO  | WO 99/35602  | 07-15-1999         | Biosite Diagnostics, Inc.                          |                       |  |
|  | AP  | EP 0 895 084 A2  | 03-02-1999         | Bayer Corporation                                  |                       |  |
|  | AQ  | WO 00/31538  | 06-02-2000         | Praxsys Biosystems                                 |                       |  |
|  | AL2 |  |                    |  |                       |  |
|  | AM2 |  |                    |  |                       |  |
|  | AN2 |  |                    |  |                       |  |
|  | AO2 |  |                    |  |                       |  |
|  | AP2 |  |                    |  |                       |  |
|  | AQ2 |  |                    |  |                       |  |
|  | AL3 |  |                    |  |                       |  |
|  | AM3 |  |                    |  |                       |  |
|  | AN3 |  |                    |  |                       |  |
|  | AO3 |  |                    |  |                       |  |
|  | AP3 |  |                    |  |                       |  |
|  | AQ3 |  |                    |  |                       |  |
|  | AL4 |  |                    |  |                       |  |
|  | AM4 |  |                    |  |                       |  |
|  | AN4 |  |                    |  |                       |  |
|  | AO4 |  |                    |  |                       |  |
|  | AP4 |  |                    |  |                       |  |
|  | AQ4 |  |                    |  |                       |  |

|          |                 |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

|   |  |  |                                  |               |
|---|--|--|----------------------------------|---------------|
| PTO-1449 REPRODUCED<br><br><b>INFORMATION DISCLOSURE CITATION<br/>IN AN APPLICATION</b><br><br><b>June 8, 2004</b><br><br>(Use several sheets if necessary) | ATTORNEY DOCKET NO.<br>2065.2001-006   |  | APPLICATION NO.<br>10/714,318    |               |
|   | FIRST NAMED INVENTOR<br>Paul C. Harris |  | FILING DATE<br>November 14, 2003 |               |
|   | EXAMINER                               |  | CONFIRMATION NO.                 | GROUP<br>1641 |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |  |  |
|--|--|--|
| AR   | Reeves, S.G. and Durst, R.A., "Novel Optical Measurement Approach for the Quantitation of Liposome Immunomigration Assays," <i>Analytical Letters</i> , 28(13):2347-2362 (1995).                         |  |
| AS   | Melamies, L., <i>et al.</i> , "Evaluation of a Quantitative Photometric Latex Agglutination Immunoassay for $\alpha$ -Foetoprotein," <i>J. Clin. Chem. Clin. Biochem.</i> , 25(3):173-176 (1987).        |  |
| AT   | Abe, J., <i>et al.</i> , "Rapid Quantitation of Serum Myoglobin by Latex Agglutination Turbidimetry," <i>Clinica Chimica Acta</i> , 203:95-96 (1991).  |  |
| AU   | Borque, L., <i>et al.</i> , "Automated Quantitative Nephelometric Latex Immunoassay for Determining Ferritin in Human Serum," <i>J. Clin. Lab. Analysis</i> , 6:239-244 (1992).                          |  |
| AV   | Roberts, M.A. and Durst, R.A., "Investigation of Liposome-Based Immunomigration Sensors for the Detection of Polychlorinated Biphenyls," <i>Anal. Chem.</i> , 67(3):482-491 (1995).                      |  |
| AW   | Siebert, S.T.A., <i>et al.</i> , "Liposome Immunomigration Field Assay Device for Alachlor Determination," <i>Analytica Chimica Acta</i> , 282:297-305 (1993).   |  |
| AX   | Siebert, S.T.A., <i>et al.</i> , "Improved Liposome Immunomigration Strip Assay for Alachlor Determination," <i>Analytica Chimica Acta</i> , 311:309-318 (1995).   |  |
| AY   | Schifreen, R.S., <i>et al.</i> , "A Quantitative Automated Immunoassay for Fibrinogen/Fibrin Degradation Products," <i>Clin. Chem.</i> , 31(9):1468-1473 (1985).   |  |
| AZ   | Laitinen, M.P.A. and Vuento, M., "Immunochromatographic Assay for Quantitation of Milk Progesterone," <i>Acta Chemica Scandinavica</i> , 50:141-145 (1996).  |  |
| AR2  | Findlay, J.W.A., <i>et al.</i> , "Validation of immunoassays for bioanalysis: a pharmaceutical industry perspective", <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 21(6):1249-1273 (2000). |  |
| AS2  | Paek,S.H., <i>et al.</i> , "Development of Rapid One-Step Immunochromatographic Assay", <i>Methods</i> , 22(1):53-60 (2000).   |  |
| AT2  |  |  |
| AU2  |  |  |

|          |                 |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|